No. 12-2475

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

THOMAS YOUNG, on behalf of himself and
all others similarly situated,
Plaintiff-Appellant,

v.

JOHNSON & JOHNSON,
Defendant-Appellee.

On Appeal from the United States District Court
for the District of New Jersey
Case No. 3:11-cv-04580-JAP-LGH
Hon. Joel A. Pisano, Presiding

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLEE, URGING AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed.R.App.P. 26.1, the Washington Legal Foundation (WLF) states that it is a corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF has no parent corporation, nor has it issued any stock owned by a publicly held company.

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IDENTITY AND INTERESTS OF *AMICI CURIAE*

The interests of the Washington Legal Foundation (WLF) are set forth more fully in the accompanying motion for leave to filed this brief.[1]

In brief, WLF is a public interest law and policy center with supporters in all 50 States. WLF regularly appears in court proceedings to promote economic liberty, free enterprise, and a limited and accountable government. To that end, WLF has appeared before this and other state and federal courts in cases involving preemption issues, seeking to point out the inefficiencies created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

WLF is particularly concerned that the American economy suffers when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that interferes with the operation of specific federal regulatory programs, such as the Nutrition Labeling and Education Act of 1990 (NLEA) at issue here.

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[1] Pursuant to Fed.R.App.P. 29(c)(5), WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

WLF supports each of the arguments raised by Appellee in its brief. WLF writes separately to focus exclusively on the second argument raised by Appellee: that Appellant's claims are expressly preempted by the NLEA.

STATEMENT OF THE CASE

Appellee Johnson & Johnson (through a wholly-owned subsidiary) manufactures and markets Benecol Regular Spread and Benecol Light Spread (collectively, "Benecol"), both of which are butter/margarine substitutes. Appellant Thomas Young filed a consumer fraud class action against Johnson & Johnson, alleging that Benecol's labeling included false and misleading statements regarding its health benefits and nutritional content. In particular, the complaint focused on several statements on Benecol's packaging label that Young alleged to be false, including: (1) "Proven to Reduce Cholesterol"; and (2) "NO TRANS FAT." Complaint, ¶¶ 3-6, 14-18; A26-A27, A29-A30.

Young alleges that the "NO TRANS FAT" statement is false because Benecol does, in fact, contain a small amount of trans fat (an amount that FDA has classified as "insignificant").[2] Although conceding that Benecol contains an ingredient, plant stanol esters, that has been proven to reduce "bad" (LDL)

[2] "Trans fat" is a commonly used name for "partially hydrogenated oil," an ingredient often added to foods.

cholesterol, Young alleges that "Proven to Reduce Cholesterol" is false with respect to Benecol itself, because Benecol is allegedly rendered unhealthy by virtue of its inclusion of "dangerous, non-nutritious, unhealthy partially hydrogenated oil." Complaint ¶ 17, A30. Young asserts that Johnson & Johnson's allegedly false labeling claims violate a number of provisions of New Jersey and New York law. Complaint ¶¶ 30-60, A33-A38.

In April 2012, the district court granted Johnson & Johnson's motion to dismiss the complaint pursuant to Fed.R.Civ.P. 12(b)(1) and 12(b)(6). A3-A13. The court ruled, *inter alia*, that Young's claims were expressly preempted by federal law. A10-A13. The court noted that the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, as amended by the NLEA, expressly preempts any state law "requirement" regarding food labeling "that is not identical to the requirement[s]" imposed by federal law. A11 (citing 21 U.S.C. §§ 343-1(a)(4) and (a)(5)). The court concluded that, even assuming that state law barred the "NO TRANS FAT" claim as false or misleading, any such state law would be preempted because it differs from FDA regulations that "require that trans fat levels less than 0.5 grams per serving 'shall be expressed as zero.'" *Id.* (quoting 21 C.F.R. § 101.9(c)(2)(ii)). The court further concluded that, even assuming that state law barred the "Proven to Reduce Cholesterol" claim as false or misleading,

any such state law would be preempted because it differs from FDA regulations that authorize claims that are "based on and consistent with" FDA's conclusion that "scientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels." A12 (quoting 21 C.F.R. §§ 101.14(d)(2)(i) and 101.83(b)(2)).

SUMMARY OF ARGUMENT

The FDCA, as amended by the NLEA, expressly preempts a broad range of state requirements for food labeling relating to health or nutrition-level claims. Such requirements, including those imposed pursuant to state tort law, are in most instances preempted unless they are "identical" to the requirements imposed by § 3(a) of the NLEA, 21 U.S.C. § 343(r). *See* 21 U.S.C. § 343-1(a)(5). Young's complaint is preempted because it is based on alleged state law requirements that are not "identical" to those imposed by the Food and Drug Administration (FDA) pursuant to § 343(r). Young disagrees, arguing that his claims are not preempted because they are "not inconsistent" with FDA regulations. Appellant Br. 25. The statutory test is not, however, whether state requirements are "consistent" with FDA requirements; the test is whether those requirements are "identical." In the absence of any evidence from Young that New Jersey and New York courts have adopted FDA's nuanced approach to food labeling claims, one cannot plausibly

argue that the alleged requirements of New Jersey and New York law are "identical" to federal law.

Young notes that FDA regulations require that the food labeling at issue here not be "false or misleading in any respect." *Id.* at 22 (citing 21 C.F.R. § 101.13(i)). But Young points to no FDA regulations or guidance documents suggesting that FDA would deem the Benecol labeling to be false or misleading. To the contrary, FDA regulations – by endorsing the scientific evidence that "including plant sterol/ stanol esters in the diet helps to lower blood total and LDL cholesterol levels" and by mandating that whenever a food contains less than 0.5 grams of trans fat, the trans fat content listed in the Nutrition Box "shall be expressed as zero" – strongly indicate that FDA would *not* deem the Benecol labeling to be false or misleading. *See* 21 C.F.R. §§ 101.9(c)(2)(ii) and 101.83(b)(2). Because New Jersey and New York tort law (as interpreted by Young) does not take into account those FDA endorsements, it is not "identical" to federal law and for that reason is expressly preempted by 21 U.S.C. § 343-1(a)(5).

Young faults Johnson & Johnson for failing to qualify its "NO TRANS FAT" claim by adding "per serving" language to the end of the claim. Young states that if a consumer ate several servings (he does not specify how many), it is possible that his trans fat consumption might exceed .5 grams, and thus FDA

regulations would no longer deem that consumption to be the equivalent of "zero" trans fat. Appellants Br. 22-23. Case law universally rejects Young's position that nutrient content claims on the front of a food package must include "per serving" language. Indeed, FDA itself, in its regulations governing nutrient content claims, assumes that "per serving" language need not be included. *See* 21 C.F.R. § 101.13(b)(1) (listing "contains 100 calories" as an example of an "expressed nutrient content claim").

It is conceivable, of course, that FDA might in the future amend its regulations and provide explicitly that labeling of the sort used by Johnson & Johnson shall henceforth be deemed false and misleading. But the Due Process Clause places strict limits on FDA's authority to apply such changes retroactively and thereby to impose sanctions based on food manufacturers' prior conduct. *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012) (stating that "[a] fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required"). Because a reasonable food manufacturer would have no reason to suspect, based on current FDA regulations, that the labeling at issue here would be deemed false or misleading by FDA, the agency could not – consistently with due process constraints – impose monetary sanctions on Johnson & Johnson for having used

that labeling. Accordingly, any state tort lawsuit that seeks to impose liability based on claims that Johnson & Johnson's labeling is false or misleading is preempted by federal law because it is not "identical" to federal requirements currently imposed by the NLEA and implementing FDA regulations.

Finally, imposing liability under the facts of this case would undermine one of Congress's principal purposes in adopting the NLEA, which was to create nationwide nutrition labeling standards for products marketed on a nationwide basis. The economy would not be well served if food purveyors were required to print 50 different sets of labels to accommodate each State's definition of what constitutes "false or misleading" nutritional information. Young insists, of course, that he is not asking for establishment of unique standards under New Jersey and New York law, but simply to allow those States to enforce laws that mirror precisely the contours of federal law. The difficulty with that approach, however, is that 51 different decision-makers will inevitably arrive at conflicting interpretations of just what labeling is permitted under federal law. Congress sought to head off that result by preempting all state-law requirements unless they are "identical" to (not merely "not in conflict with" or "not inconsistent with") federal law. In the absence of evidence from Young suggesting that the state-law requirements he espouses really are "identical" to the federal government's

understanding of what constitutes "false or misleading" nutrition labeling, a preemption finding is the only way to avoid creating the crazy-quilt system of non-uniform labeling requirements that Congress sought to avoid.

ARGUMENT

I. APPELLANT'S CLAIMS ARE EXPRESSLY PREEMPTED BY THE FDCA

Subject to exceptions not applicable to this case, the FDCA expressly preempts any state "requirement respecting any claim of the type described in [21 U.S.C. § 343(r)(1), which governs "Nutrition levels and health-related claims"] made in the label or labeling or food that is not *identical* to the requirement of" § 343(r). 21 U.S.C. § 343-1(a)(5) (emphasis added). Because the requirements that Appellant Young seeks to impose pursuant to New Jersey and New York law are not "identical" to the requirements imposed by § 343(r) and implementing regulations, Young's claims are expressly preempted, and the district court's dismissal of his lawsuit should be affirmed.

Appellant Young denies that his claims are expressly preempted, but his brief devotes remarkably little attention to the wording of the express preemption provision at issue in this case. In adopting that approach, Young's brief fails to address the principal issue in this appeal. As the U.S. Supreme Court recently

explained, "When a federal law contains an express pre-emption clause, we focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." *Chamber of Commerce of the United States v. Whiting*, 131 S. Ct. 1968, 1977 (2011) (citations omitted). Moreover, "[t]he purpose of Congress is the ultimate touchstone of preemption analysis." *Cipillone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

As Young notes, courts will often apply a "presumption" against preemption, so that when confronted with two equally plausible interpretations of an express preemption provision, they will "accept the reading that disfavors pre-emption." Appellants Br. 19 (quoting *Bates*, 554 U.S. at 449). The presumption against preemption does not come into play in this case, however, because Young has not pointed to any alleged ambiguities in the language of § 343-1(a)(5). Young does not contest that the labeling at issue in this case is "of the type described" in 21 U.S.C. § 343(r)(1) (which governs "Nutrition levels and health-related claims") – thereby making it subject to § 343-1(a)(5) preemption. Nor does he contest that the statutory word "identical" is unambiguous; *i.e.*, any state labeling requirement is preempted unless it is *precisely the same* as the analogous federal requirement. Finally, the Supreme Court has determined that when (as here) a federal express preemption statute uses the term "requirement," that term encompasses not only

rules established by state statutes but also duties imposed by common-law courts. *Riegel v. Medtronic, Inc.*, 552 U.S. at 324 ("Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties.").

A. Common Law Rules Asserted by Appellant Are Not "Identical" to Federal Requirements Governing Appellee's Labeling

An understanding of why it is that Young's claims are preempted by federal law (because they are not "identical" to federal requirements) requires a brief explanation of the NLEA. That federal statute, adopted in 1990, greatly expanded the scope of nutritional labeling required for food offered for sale. Every food covered by the NLEA must bear a uniformly-formatted nutrition label (generally referred to as the "Nutrition Box") that discloses the amount of calories, fat, salt, and other nutrients. In order to make this information meaningful, the NLEA requires FDA to issue standards providing that uniform serving-size information and information concerning the number of servings be furnished in the Nutrition Box. These Nutrition Box requirements are set for in § 2 of the NLEA, codified at 21 U.S.C. § 343(q).

The NLEA also sets forth detailed provisions governing nutrient claims

made by food manufacturers outside the context of the Nutrient Box. Those provisions are contained in § 3 of the NLEA, codified at 21 U.S.C. § 343(r). The statute divides such claims into two basic types: (1) nutrient content claims (*e.g.*, "contains 100 calories"); and (2) disease/health claims (*e.g.*, "fiber prevents cancer"). Section 343(r) directs FDA to issue regulations identifying nutrient content claims and disease/health claims that meet the requirements of the NLEA. Benecol's "NO TRANS FAT" labeling is an example of a nutrient content claim; its "Proven to Reduce Cholesterol" labeling is an example of a disease/health claim.

FDA has issued detailed regulations governing nutrient content claims regarding trans fat and governing health claims regarding foods containing plant sterol/stanol esters. *See* 21 C.F.R. §§ 101.9(c)(2)(ii) and 101.83(b)(2). FDA regulations also include a general prohibition against inclusion of "false or misleading" information in certain food labeling that is subject to 21 U.S.C. § 343(r). *See* 21 C.F.R. § 101.13(i)(3). The issue to be decided by this Court is whether the state law requirements that Young is seeking to impose on Johnson & Johnson are "identical" to the federal requirements established by 21 U.S.C.

§ 343(r) and FDA's implementing regulations.[3] Unless those state law requirements are "identical," they are expressly preempted by § 343-1(a)(5).

Young urges the Court to adopt a relaxed preemption standard, whereby his claims should not be deemed preempted if they do not directly conflict with (are "not inconsistent with") some federal requirement. Appellants Br. 25. That standard is not the one imposed by the NLEA's express preemption provision, as the Seventh Circuit has recognized. *Turek v. General Mills, Inc.*, 662 F.3d 423 (7th Cir. 2011) (Posner, J.) ("Even if the disclaimers that the plaintiff wants added would be consistent with the requirements imposed by the Food, Drug, and Cosmetic Act, consistency is not the test [imposed by §343-1(a)(5)]; identity is."). The New Jersey and New York common law rules being pressed by Young can be termed "identical" to federal requirements only if there is a strong basis for concluding that the labeling to which Young objects would be deemed false and misleading under federal law. *See Bates*, 544 U.S. 431, 454 (in explaining the circumstances under which a state pesticide labeling laws would *not* be deemed

[3] For purposes of preemption analysis, courts have generally understood the relevant federal "requirements" to encompass not only federal statutes but also implementing regulations and administrative determinations. *See, e.g.*, *Geier*, 529 U.S. at 874; *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 244 (3d Cir. 2008) ("there is no doubt that federal statutes as well as statutes can establish law having preemptive force.").

preempted under an analogous express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Court states, "a manufacturer should not be held liable under a state labeling requirement subject to [FIFRA's preemption provision] unless the manufacturer is also liable for misbranding as defined by FIFRA"). Because there is little or no evidence suggesting that FDA would deem the Benecol labeling to be false or misleading, Young's claims are expressly preempted by § 343-1(a)(5).

1. The NLEA Does Not Prohibit the "NO TRANS FAT" Claim as False or Misleading

Benecol's Nutrition Box lists the product's trans fat content as "0g" per serving. Young concedes that that listing is proper under FDA regulations. Benecol does contain very small quantities of trans fat, but because the quantity is less than .5 grams per serving, FDA regulations provide that the trans fat content listed in the Nutrition Box "shall be expressed as zero." 21 C.F.R. § 101.9(c)(2)(ii).

FDA has not provided explicit guidance for trans fat content claims appearing outside the Nutrition Box.[4] But given FDA's endorsement of a "zero"

[4] FDA regulations provide generally that labeling outside the Nutrition Box "may contain a statement about the amount or percentage of a nutrient" provided that certain conditions are met, including that in instances in which it does not conform precisely to the Nutrition Box format, it is nonetheless not "false or

content claim within the Nutrient Box for foods containing less than .5 grams of trans fat per serving, there is no reason to conclude that FDA would deem an equivalent claim to be false or misleading if included elsewhere on the labeling. Indeed, in connection with rules governing use of a "simplified format" for the Nutrition Box, FDA regulations declare that foods containing less than .5 grams of trans fat per serving contain an "insignificant amount" of trans fat. 21 C.F.R. § 101.9(f).

Young faults Johnson & Johnson for failing to qualify its "NO TRANS FAT" claim by adding "per serving" language to the end of the claim. Young states that if a consumer ate several servings, it is possible that his trans fat consumption might exceed .5 grams, and thus FDA regulations would no longer deem that consumption to be the equivalent of "zero" trans fat. Appellants Br. 22-23.

WLF notes initially that Young's complaint does not specify how much trans fat he alleges is in each serving of Benecol or how many servings would be required before a consumer would exceed the .5 gram threshold. Accordingly, the complaint does not adequately allege that a consumer would exceed the threshold even if he consumed an entire package of Benecol.

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misleading." 21 C.F.R. § 101.13(i) & (i)(3).

But even if such a consumer might eventually exceed the .5 gram threshold, there is no evidence to suggest that FDA deems a nutrition content claim to be misleading if it fails to include "per serving" language. Indeed, in its regulations governing nutrient content claims, FDA assumes that "per serving" language need not be included in many cases. *See* 21 C.F.R. § 101.13(b)(1) (listing "contains 100 calories" as an example of an "expressed nutrient content claim"); § 101.13(i)(3) (listing "100 calories" and "5 grams of fat" as acceptable nutrient content claims, provided only that the claim "is not false or misleading in any respect"). Given the universal understanding that content claims refer to the content per serving unless otherwise stated, there is no reason to conclude that consumers would be misled by omission of the "per serving" language.[5]

Numerous federal courts, in addition to the court below, have rejected allegations that a trans fat content claim is "false or misleading" under federal law merely because it does not include "per serving" language. *See, e.g., Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 Fed. Appx. 113 (9th Cir. 2012)*; Chacanaca v. Quaker Oats Co.,* 752 F. Supp. 2d 1111 (N.D. Cal. 2010)*; Reid v. Johnson &*

[5] By Young's logic, claims that a product contains "100% of the daily requirement for Vitamin C" are appropriate if the product package contains 20 servings and each serving provides 5% of daily Vitamin C requirements. But such claims would be highly misleading to a typical consumer, who would reasonably conclude that the claim provided per serving information.

Johnson, Civil No. 11-1310-L (BLM), 2012 U.S. Dist. LEXIS 133408 (S.D. Cal. Sept. 18, 2012). If federal law does not require "per serving" language, then state law attempting to impose such a requirement is preempted because it would not be "identical" to federal law.

Nor is it relevant that Benecol labeling states "no" trans fat instead of "0 grams" trans fat. Young insists that consumers are deceived by the term "no" trans fat because they are likely to believe that multiple servings of a product with "no" trans fat per serving would still provide "no" trans fat – when, in fact, multiple servings might put one's trans fat intake above the .5 grams threshold that FDA deems "insignificant." Appellant Br. 22-23. That argument is without merit. As the district court recognized, the words "no" and "zero" are synonymous. A11 n.5. The potential source of confusion identified by Young is present to the same extent when product labeling claims "0 grams" trans fat as it is when product labeling claims "no" trans fat. If, as demonstrated above, it is not misleading under federal law to state that a product contains "0 grams" trans fat even though multiple servings of the product might take one's trans fat intake above the .5 gram threshold, then so too it is not misleading under federal law to label that same product as containing "no" trans fat.

The likelihood that FDA would deem Benecol labeling to be false or

misleading is even further reduced when one considers that the labeling stated explicitly in several locations – including in the Nutrition Box – that the product contained "partially hydrogenated oils." Federal courts have recognized that most nutrition-conscious consumers look first to the Nutrition Box if they wish to get a complete listing of ingredients. *See, e.g., Hairston v. South Beach Beverage Co.*, No. CV 12-1429-JFW, 2012 WL 1893818 at *5 (C.D. Cal. May 18, 2012) (stating that "reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging"). A potential purchaser who saw the "NO TRANS FAT" claim on the Benecol labeling and was sufficiently enticed to consider purchasing the product on the basis of that claim almost certainly would turn to the Nutrition Box to obtain more detailed information. Doing so would confirm to the potential purchaser the accuracy of the "NO TRANS FAT" claim as well as providing an additional detail: that the product contains an nutritionally insignificant amount of trans fat. Young apparently takes the view that no amount of trans fat in one's diet is insignificant.[6]

[6] WLF notes, however, that the complaint does not explicitly allege that Young relied on the "NO TRANS FAT" claim (as opposed to relying on the Nutrition Box information whose accuracy he does not challenge) in deciding to purchase Benecol. Given his failure to allege such a key component of the causal chain, it is difficult to comprehend how Young can assert that he meets the second requirement of Article III standing: the alleged injury must be fairly traceable to the alleged misconduct. *Lujan v. Defenders f Wildlife*, 504 U.S. 555, 560 (1992).

But as FDA's regulations indicate, that is not FDA's position. To the extent that either New Jersey or New York law takes a position that is anything other than "identical" to FDA's position, it is preempted.

2. The NLEA Does Not Prohibit the "Proven to Reduce Cholesterol" Claim as False or Misleading

FDA has issued a regulation that recognizes the health benefits derived from consuming plant sterol/stanol esters and that authorizes food purveyors to make health claims that tout those benefits. *See* 21 C.F.R. § 101.83 (entitled, "Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD)."). The regulation declares unequivocally that "[t]he scientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels." 21 C.F.R. § 101.83(b)(2). Benecol's labeling makes health claims far more modest than those permitted by the regulation. Instead of making claims associating Benecol consumption with reduced risk of coronary heart disease, it merely claims that Benecol "reduces cholesterol." In light of FDA's adoption of § 101.83, it simply is not plausible that FDA would deem the "Proven to Reduce Cholesterol" claim to be false or misleading.

Young faults Johnson & Johnson for failing to specify that it is the plant sterol/stanol esters contained in Benecol – rather than the entirety of the Benecol

product – that has been proven to lower blood total and LDL ("bad") cholesterol levels. Appellant Br. 28. But FDA itself has never made that distinction. Section 101.83 authorizes claims that associate "diets that include plant sterol/stanol esters with reduced risk of heart disease." 21 C.F.R. § 101.83(c)(2)(i). Because diets that include Benecol are by definition "diets that include plant sterol/stanol esters," there is no reason to conclude that FDA disapproves of labeling claims that focus on the product that contains the favored ingredient rather than on the favored ingredient in isolation.[7]

Young also contends that the presence of insignificant amounts of trans fat in Benecol cancels out the health benefits that otherwise would be derived from the presence of plant sterol/stanol esters and thereby renders false and misleading the "Proven to Reduce Cholesterol" claim. Appellant Br. 27 n.9. But again, Appellant has provided no evidence that FDA supports his "cancels out the health benefits" theory and would on that basis deem the labeling claim to be false or misleading. Indeed, *Chacanaca* convincingly refuted that theory and explained why FDA should not be deemed to disapprove of claims made in connection with foods containing small amounts of trans fat:

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[7] Moreover, as Johnson & Johnson points out, Appellee Br. 35, a full reading of the Benecol label makes clear that the "Proven to Reduce Cholesterol" claim is based on the presence of plant stanol esters in Benecol.

> [Federal law] categorizes as misleading and therefore prohibited even true nutrient content claims if the presence of another "disqualifying" nutrient exceeds an amount established by regulation. . . . It is important to note how disqualifying claims work. A disqualifying level of, say, saturated fat is four grams per "reference amount customarily consumed." 21 C.F.R. § 101.13(h)(1). If this level is exceeded, a food purveyor is *prohibited* from making an unqualified claim touting the health benefits of another nutrient in the food. This is because the Agency has reasoned that the beneficent claim, standing alone, would be misleading. Notably, FDA in a recent final rule declined to set disqualifying levels for trans fat. . . . As a matter of federal law, then, the presence of trans fat alone is not a "disqualifying" nutrient which would prevent Quaker Oats from emphasizing whatever other health benefits are available from the Bars' other ingredients or because it lacks certain ingredients. Because the Agency has expressly decided *not* to recognize trans fat as a disqualifying nutrient, plaintiffs' state law claim is inconsistent with [21 U.S.C. § 343(r)] and its regulations to the extent it depends on the presence of trans fat to render the content claims misleading.

Chacanaca, 752 F. Supp. 2d at 1122. Similarly, in the absence of evidence that the presence of an insignificant amount of trans fat would cause FDA to disapprove Benecol's "Proven to Reduce Cholesterol" claim, any state law rule evidencing such disapproval is not "identical" to federal law and is therefore preempted.

3. The FDA Letters Cited by Appellant Are Not Relevant to the Preemption Issue

In urging reversal of the district court's decision, Young seeks to rely on two letters drafted by FDA personnel that he failed to present to the district court. Neither letter supports his position that FDA would deem the Benecol labeling to be false or misleading.

WLF notes initially that the letters do not represent FDA policy but rather are the individual views of the authors of those letters. Courts are unanimous in characterizing "warning letters" sent by FDA personnel as tentative expressions of opinion that do not represent official agency policy – and therefore are not final agency action subject to judicial review. *See, e.g. Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012), *cert denied*, No. 11-1454 (U.S. Oct. 15, 2012); *Cody Labs., Inc. v. Sebelius*, 446 Fed. Appx. 964, 969 (10th Cir. 2011) (stating that "every court to consider the question has held that an FDA warning letter does not constitute final agency action."). Indeed, in its recent brief opposing Supreme Court review in *Holistic Candlers*, the United States stated unequivocally: "the warning letters were not based on a formal and complete administrative record. At this stage, FDA's statement that petitioners violated the FDCA was not final and binding on the agency or petitioners but rather remained tentative and interlocutory in nature." Brief for the United States in Opposition, *Holistic Candlers and Consumers Ass'n v. FDA*, Supreme Court No. 11-1454 (filed Sept. 10, 2012). Because the letters cited by Young do not represent official FDA policy, they do not provide evidence that FDA would disapprove of Benecol's labeling.

More importantly, the letters themselves contain no hint that the authors of

the "warning letters" believed that the labeling in question was false or misleading, and Young has failed to demonstrate how they relate directly to the preemption issues in this case. The May 5, 2009 letter from a Minneapolis-based FDA employee to General Mills[8] took issue with a cholesterol-lowering claim on the labeling for Cheerios cereal: "You can Lower Your Cholesterol 4% in 6 weeks." The letter stated that although FDA had "issued a regulation authorizing a health claim associating soluble fiber with a reduced risk of coronary heart disease (21 CFR 101.81)," the particular claim made by General Mills was not one of the authorized claims. Of course, FDA's soluble fiber regulation is not at issue in this case, so the specific claims authorized by that regulation is of limited relevance to Young's lawsuit. Furthermore, the letter did not suggest that the FDA employee believed that General Mills's claim was false or misleading, only that it had not been authorized by FDA.

The other letter cited by Young – a February 4, 2009 letter from an FDA employee based in Bothell, Washington to BestLife International[9] – is of even less relevance to this case. It did not focus on product package labeling but rather on

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[8] Available at http://www.fda.gov/iceci/enforcementactions/warningletters/ucm162943.htm.

[9] Available at http://www.fda.gov/iceci/enforcementactions/warningtletters/2009/ucm148648.htm.

material that appeared on the company's web site. The gist of the letter was that health claims made on the web site caused certain soy-based products to be classified as "drugs" under the FDCA, and therefore that BestLife was violating the FDCA by selling drugs that had not been approved by FDA. Nothing in the letter indicated that the FDA employee believed that the statements made on the web site were either false or misleading. The only references to "no trans fat" appear as an afterthought in two short sentences at the very end of the letter. Although the FDA employee opined that the "no trans fat" claim was not authorized because it did not reference the quantity of trans fat "per serving," he made no effort to square that opinion with the FDA regulations[10] indicating that "per serving" language need not be included in many cases. Moreover, the FDA employee never indicated that he deemed the "no trans fat" claim to be false or misleading. In short, nothing in either letter cited by Young supports his efforts to escape preemption by asserting that state laws that allegedly deem Johnson & Johnson's labeling claims to be false and misleading are "identical" to federal law.

B. Appellant's Claims Are Expressly Preempted for the Additional Reason that Any Effort to Impose Retroactive Liability on Appellee Would Raise Serious Due Process Concerns

As demonstrated above, there is no evidence that, based on current FDA

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[10] 21 C.F.R. § 101.13(b)(1) & (i)(3).

regulations, the Agency would consider the Benecol labeling to be false or misleading. It is conceivable, of course, that FDA might in the future amend its regulations and provide explicitly that labeling of the sort used by Johnson & Johnson should henceforth be deemed false and misleading. Even if that were to occur, Young's claims would still be preempted because due process constraints would prevent FDA or anyone else from imposing retroactive liability on the basis of such new rules.

The Supreme Court's recent *Fox Television* decision thoroughly articulates those due process constraints. In that case, the FCC was seeking to impose liability on two television networks for violating the FCC's new "fleeting expletives" and "fleeting nudity" policies, even though the new policies were not in place at the time that the networks aired the shows in question.[11] The Court unanimously held that the Due Process Clause prohibited the FCC from attempting to fine the networks for the speech in question because it had failed to give them fair warning of the new FCC policy. The Court explained, "A fundamental principle of our legal system is that laws which regulate persons or entities must give fair notice of

[11] The case involved three separate incidents. Two involved obscene words uttered spontaneously during awards shows aired by Fox Television Stations. The third involved a scripted show on the ABC Television Network, in which the buttocks of a female character were exposed for several seconds.

the conduct that is forbidden or required." *Fox Television*, 132 S. Ct. at 2317. The Court held that the federal government's efforts to impose retroactive fines was particularly objectionable because the fines were being imposed on the basis of First Amendment-protected activities:

> [T]he Commission policy in place at the time of the broadcasts gave no notice to Fox or ABC that a fleeting expletive or a fleeting shot of nudity could be actionably indecent; yet Fox and ABC were found to be in violation. The Commission's lack of notice to Fox and ABC that its interpretation had changed . . . failed to provide a person of ordinary intelligence fair notice of what is prohibited. This would be true with respect to a regulatory change this abrupt *on any subject*, but it is surely the case when applied to the regulations in question, regulations that touch upon sensitive areas of basic First Amendment freedoms.

Id. at 2318 (emphasis added and citations omitted).

Similarly, because current FDA regulations provide Johnson & Johnson with no notice that federal officials deem its Benecol labeling to be false or misleading, the Due Process Clause would prevent FDA from adopting a new policy and then attempting to fine Johnson & Johnson on the basis that the labeling was classified as false or misleading speech under the new policy. The most that FDA would be permitted to do would be to direct Johnson & Johnson to comply with the new policy prospectively.

Because federal law could not constitutionally be used to impose retroactive liability on Johnson & Johnson, Young's efforts to invoke New Jersey and New

York law to impose monetary sanctions on the company are preempted; they are based on alleged state law that is not "identical" to federal law. Moreover, States are subject to the same due process constraints as is the federal government. Accordingly, unless Young can demonstrate that the Johnson & Johnson has received fair notice that labeling of the sort in which it has engaged has already been deemed false and misleading under some existing principles of New Jersey and New York law, his claims would be barred for the additional reason that due process prevents courts from invoking the laws of those two States for the purpose of imposing retroactive liability on the company.

II. IMPOSING COMMON LAW LIABILITY ON APPELLEE WOULD UNDERMINE CONGRESS'S INTENT TO CREATE NATIONWIDE LABELING STANDARDS

Imposing liability under the facts of this case would undermine one of Congress's principal purposes in adopting the NLEA, which was to create nationwide nutrition labeling standards for products marketed on a nationwide basis. The economy would not be well served if food purveyors were required to print 50 different sets of labels to accommodate each State's definition of what constitutes "false or misleading" nutritional information.

Congress's desire for uniform labeling requirements is evidenced by the title of Section 6 of the NLEA, the section that includes the NLEA's express

preemption provisions. Section 6 is entitled, "National Uniform Nutrition Labeling." Section 6 includes five extremely broad preemption provisions, including the one (21 U.S.C. § 343-1(a)(5)) at issue in this case. All five of those preemption statutes provide that state regulation of nutrition labeling can survive preemption only if it is "identical" to the corresponding federal requirement. By so providing, Congress could not have been clearer that it desired that food labeling in this country would henceforth be uniformly enforced in all 50 States pursuant to but one labeling policy.

Courts have repeatedly acknowledged that creation of a nationwide uniform labeling policy was an important goal of Congress in adopting the NLEA. As Judge Posner has observed:

> It is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy.

Turek v. General Mills, 662 F.3d at 426.

Young insists, of course, that he is not asking for establishment of unique standards under New Jersey and New York law, but simply asking that those States be allowed to enforce laws that mirror precisely the contours of federal law. The difficulty with that approach, however, is that 51 different decision-makers will

inevitably arrive at conflicting interpretations of just what labeling is permitted under federal law. Congress sought to head off that result by preempting all state-law requirements unless they are "identical" to (not merely not in conflict with) federal law. In the absence of evidence from Young suggesting that the state-law requirements he espouses really are "identical" to the federal government's understanding of what constitutes "false or misleading" nutrition labeling, a preemption finding is the only way to avoid creating the crazy-quilt system of non-uniform labeling requirements that Congress sought to avoid.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court affirm the judgment of the district court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I am an attorney for *amici curiae* Washington Legal Foundation (WLF), *et al*. Pursuant to Fed.R.App.P. 32(a)(7)(C), I hereby certify that the foregoing brief of WLF is in 14-point, proportionately spaced Times New Roman type. According to the word processing system used to prepare this brief (WordPerfect X5), the word count of the brief is 6,440, not including the corporate disclosure statement, table of contents, table of authorities, certificate of service, certificate of bar membership, and this certificate of compliance. The hard copy and the electronic copy of this brief are identical. The electronic copy has been virus scanned using etrust antivirus software, version 7.1.192.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF BAR MEMBERSHIP

I hereby certify that I am a member of the bar of this Court.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of October, 2012, 10 copies of the brief of *amicus curiae* WLF in support of Appellee were deposited in the U.S. Mail, addressed to the Court. I further certify that on October 31, 2012, I electronically filed the brief of *amicus curiae* Washington Legal Foundation with the Clerk of the Court of the U.S. Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Richard A. Samp
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